IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent No. 5,510,106)
)
Issued: April 23, 1996)
)
To: Janet K. Yamamoto et al.)
)
Assignee: The Regents of the University of California)
)
For: METHODS AND COMPOSITIONS FOR VACCINATING AGAINST FELINE IMMUNODEFICIENCY VIRUS)

MAIL STOP PATENT EXT.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

CERTIFICATION

I hereby certify that this accompanying application for extension of the term of U.S. Patent 5,510,106 under 35 U.S.C. § 156 including its attachments and supporting papers is being submitted as one original and two (2) copies thereof.

Respectfully submitted,

Date: Aug 20, 2003

By: _____
Kevin L. Bastian
Reg. No. 34,774

60022708 v1

1457 08-22-03

PTO/SB/21 (05-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	08/335,296/U.S. Patent No. 5,510,106
Filing Date	November 7, 1994 (Issue Date: April 23, 1996)
First Named Inventor	YAMAMOTO
Art Unit	
Examiner Name	
Total Number of Pages in This Submission: 55	Attorney Docket Number: 02307U-023770US

ENCLOSURES *(Check all that apply)*

- ☒ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s)
- ☐ After Allowance Communication to Group
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to Group (**Appeal Notice, Brief, Reply Brief**)
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below)*:

Application for Extension of Patent Term Under 35 USC 1.56 (8pp); Attachment A - POA, Statement Under 37 CFR 3.73 (2pp); Attachment B- Approval Letter and License (2pp); Attachment C - US Patent No. 5,510,106 (26pp); Attachment D - Terminal Disclaimer (2pp); Attachment E - Certificate of Correction (1pg); Attachment F - Receipt of Maintenance Fee Payments (1pg); Attachment ?G - Chronology of Regulatory Review Period (1pg); Attachment H - Certificate of Copies of Application Papers (1pg); Return Postcard

Remarks: The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual	Townsend and Townsend and Crew LLP Kevin Bastian Reg. No. 34,774
Signature	
Date	August 20, 2003

CERTIFICATE OF MAILING

Express Mail Label: EV 332108727 US

I hereby certify that this correspondence is being deposited with the United States Postal Service with "Express Mail Post Office to Address" service under 37 CFR 1.10 on this date August 20, 2003 and is addressed to:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Typed or printed name	Stephanie A. Whitehurst		
Signature		Date	August 20, 2003

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

60022962 v1

PTO/SB/17 (05-03)
Approved for use through 04/30/2003. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

FEE TRANSMITTAL for FY 2003

Effective 01/01/2003. Patent fees are subject to annual revision.

☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT ($) 1120

Complete if Known	
Application Number	08/335,296 (U.S. Patent No. 5,510,106)
Filing Date	November 7, 1994 (Issue Date: April 23, 1996)
First Named Inventor	YAMAMOTO
Examiner Name	
Art Unit	
Attorney Docket No.	023070-023770US

RECEIVED
AUG 26 2003
OFFICE OF PETITIONS

AUG 20 2003

METHOD OF PAYMENT *(check all that apply)*

☐ Check ☐ Credit Card ☐ MoneyOrder ☐ Other ☐ None

☒ Deposit Account:

Deposit Account Number: 20-1430

Deposit Account Name: Townsend and Townsend and Crew LLP

The Commissioner is authorized to: *(check all that apply)*

☒ Charge fee(s) indicated below ☒ Credit any overpayments

☒ Charge any additional fee(s) during the pendency of this application

☐ Charge fee(s) indicated below, **except for the filing fee** to the above-identified deposit account.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1001	750	2001	375	Utility filing fee	
1002	330	2002	165	Design filing fee	
1003	520	2003	260	Plant filing fee	
1004	750	2004	375	Reissue filing fee	
1005	160	2005	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES FOR UTILITY AND REISSUE

		Extra Claims	Fees from below	Fee Paid
Total Claims	-** =		X =	
Independent Claims	-** =		X =	
Multiple Dependent			X =	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
1202	18	2202	9	Claims in excess of 20
1201	84	2201	42	Independent claims in excess of 3
1203	280	2203	140	Multiple dependent claim, if not paid
1204	84	2204	42	** Reissue independent claims over original patent
1205	18	2205	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
1051	130	2051	65	Surcharge - late filing fee or oath	
1052	50	2052	25	Surcharge - late provisional filing fee or cover sheet.	
1053	130	1053	130	Non-English specification	
1812	2,520	1812	2,520	For filing a request for reexamination	
1804	920*	1804	920*	Requesting publication of SIR prior to Examiner action	
1805	1,840*	1805	1,840*	Requesting publication of SIR after Examiner action	
1251	110	2251	55	Extension for reply within first month	
1252	410	2252	205	Extension for reply within second month	
1253	930	2253	465	Extension for reply within third month	
1254	1,450	2254	725	Extension for reply within fourth month	
1255	1,970	2255	985	Extension for reply within fifth month	
1401	320	2401	160	Notice of Appeal	
1402	320	2402	160	Filing a brief in support of an appeal	
1403	280	2403	140	Request for oral hearing	
1451	1,510	1451	1,510	Petition to institute a public use proceeding	
1452	110	2452	55	Petition to revive – unavoidable	
1453	1,300	2453	650	Petition to revive – unintentional	
1501	1,300	2501	650	Utility issue fee (or reissue)	
1502	470	2502	235	Design issue fee	
1503	630	2503	315	Plant issue fee	
1460	130	1460	130	Petitions to the Commissioner	
1807	50	1807	50	Petitions related to provisional applications	
1806	180	1806	180	Submission of Information Disclosure Stmt	
8021	40	8021	40	Recording each patent assignment per property (times number of properties)	
1809	750	2809	375	Filing a submission after final rejection (37 CFR § 1.129(a))	
1810	750	2810	375	For each additional invention to be examined (37 CFR § 1.129(b))	
1801	750	2801	375	Request for Continued Examination (RCE)	
1802	900	1802	900	Request for expedited examination of a design application	
Other fee (specify) Application for Extension of Patent					1120

*Reduced by Basic Filing Fee Paid **SUBTOTAL (3)** ($)1120

SUBMITTED BY				Complete *(if applicable)*	
Name (Print/Type)	Kevin Bastian	*Registration No. (Attorney/Agent)*	34,774	*Telephone*	415-576-0200
Signature				*Date*	August 20, 2003

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

This collection of information is required by 37 CFR 1.17 and 1.27. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.** 60022727 v1

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.

#9

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re U.S. Patent No. 5,510,106)
)
Issued: April 23, 1996)
)
To: Janet K. Yamamoto et al.)
)
Assignee: The Regents of the University of California)
)
For: METHODS AND COMPOSITIONS FOR VACCINATING AGAINST FELINE IMMUNODEFICIENCY VIRUS)

ATTN: MAIL STOP PATENT EXT.
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

APPLICATION FOR EXTENSION OF PATENT
TERM UNDER 35 U.S.C. § 156

Applicant, The Regents of the University of California, represents that it is the Assignee of the entire interest in and to United States Patent No. 5,510,106 (assignment recorded in the United States Patent and Trademark Office at Reel 7238, Frame 0859) granted to Janet K. Yamamoto and Niels D. Pedersen on the 23rd day of April, 1996, for Methods and Compositions for Vaccinating Against Feline Immunodeficiency Virus. By the Power of Attorney enclosed herein (Attachment A), Applicant appoints Kevin L. Bastian as attorney for Applicant with regard to this application for extension of the term of U.S. Patent No. 5,510,106 and to transact all business in the U.S. Patent and Trademark Office in connection therewith.

Information Required Under 37 C.F.R. § 1.740

Applicant hereby submits this application for extension of the patent term under 35 U.S.C. § 156 by providing the following information required by the rules promulgated by the U.S. Patent and Trademark Office (37 C.F.R. § 1.740). For the convenience of the Patent and Trademark Office, the information contained in this application will be presented in a format which follows the requirements of Section 1.740 of Title 37 of the Code of Federal Regulations.

(1) The approved product is the Fel-O-Vax® LvK/FIV vaccine (VS Code No. 15D5.R0). The vaccine is a combination feline leukemia virus/feline immunodeficiency virus vaccine comprising inactivated feline leukemia virus, inactivated subtype A FIV persistently infected cells, and inactivated subtype D FIV persistently infected cells.

(2) The approved product was subject to regulatory review under the Virus-Serum-Toxin Act (21 U.S.C. §§ 151-159) and corresponding regulations (9 C.F.R. § 102).

(3) The approved product Fel-O-Vax® LvK/FIV vaccine received permission for commercial marketing or use under the Virus-Serum-Toxin Act on June 23, 2003. A copy of the approval letter and the U.S. Veterinary Biological Product License are attached (Attachment B).

(4) The active ingredients in Fel-O-Vax® LvK/FIV vaccine include inactivated feline leukemia virus, inactivated subtype A FIV persistently infected cells, and inactivated subtype D FIV persistently infected cells. On information and belief, this combination of active ingredients has not been approved for commercial marketing or use under the Virus-Serum-Toxin Act prior to approval by the Department of Agriculture on June 23, 2003.

A vaccine including inactivated subtype A and subtype D FIV whole virus was approved by the Department of Agriculture on March 14, 2002 (V.S. Code No. 15A5.21). A vaccine including inactivated feline leukemia virus was approved by the Department of Agriculture on September 18, 1990 (V.S. Code No. 1555.21; reissued as V.S. Code No. 1555.R1 on July 17, 2003).

(5) This application for extension of patent term under 35 U.S.C. § 156 is being submitted within the permitted 60-day period pursuant to 37 C.F.R. § 1.720(f), said period will expire on August 22, 2003.

(6) The complete identification of the patent for which a term extension is being sought is as follows:

Inventors: Janet K. Yamamoto and Niels D. Pedersen

Patent No.: 5,510,106

Issue Date: April 23, 1996

Expiration Date: January 4, 2011 (by virtue of terminal disclaimer)

(7) A true copy of the patent is attached (Attachment C).

(8) No reexamination certificate has been issued on this patent. A copy of a terminal disclaimer submitted in the application that issued as U.S. Patent No. 5,510,106 is attached (Attachment D). A copy of a Certificate of Correction for U.S. Patent No. 5,510,106 is also attached (Attachment E). A copy of a record of maintenance fee payments under 35 U.S.C. § 41(b) is attached (Attachment F).

(9) U.S. Patent No. 5,510,106 claims a vaccine and a method of administering a vaccine. Claims 1-3 read on the Fel-O-Vax® LvK/FIV vaccine, or on its method of use.

Claims 1 and 2 are directed to a vaccine comprising an immunogen capable of eliciting an immune response protective against feline immunodeficiency virus (FIV) infection, wherein the immunogen provides immunological protection against FIV, and reads on the approved product because the approved product is a combination feline leukemia virus/feline immunodeficiency virus vaccine comprising inactivated feline leukemia virus, inactivated subtype A FIV persistently infected cells, and inactivated subtype D FIV persistently infected cells.

Claim 3 is directed to a method of administering the vaccine of claim 1 to a cat and reads on a method of using the approved product for the reasons noted above.

(10) The relevant dates and information pursuant to 35 U.S.C. § 156(g) to enable the Secretary of Agriculture to determine the applicable regulatory review period are as follows:

The "date the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act became effective", as stated in 37 C.F.R. § 1.740(a)(10)(iii), is considered to be October 15, 1999. We have used the date of October 15, 1999, which is the date an Application for United States Veterinary Biological Product License (VS 1A55.20) was submitted to USDA involving the approved product.

A U.S. Veterinary Biological Product License application for Fel-O-Vax® LvK/FIV vaccine was submitted on October 15, 1999, and such license (V.S. Code No. 15D5.R0) was issued on June 23, 2003.

(11) A brief description of the significant activities undertaken by the marketing applicant during the applicable regulatory review period with respect to Fel-O-Vax® LvK/FIV vaccine and the dates applicable to these significant activities are set forth in a chronology of events in Attachment G.

(12)(i) Applicant is of the opinion that U.S. Patent No. 5,510,106 is eligible for extension of the patent term under 35 U.S.C. § 156 because it satisfies all requirements for such extension as follows:

(a) 35 U.S.C. § 156(a) - U.S. Patent No. 5,510,106 claims a method for using the Fel-O-Vax® LvK/FIV vaccine, as well as the vaccine itself.

(b) 35 U.S.C. § 156(a)(1) - U.S. Patent No. 5,510,106 has not expired before submission of this application.

(c) 35 U.S.C. § 156(a)(2) - The term of U.S. Patent No. 5,510,106 has never been extended under 35 U.S.C. § 156(e)(1).

(d) 35 U.S.C. § 156(a)(3) - The application for extension is submitted by the agent of the owner of record of the patent in accordance with the requirements of paragraphs (1) through (4) of 35 U.S.C. § 156(d) and the rules of the Patent and Trademark Office.

(e) 35 U.S.C. § 156(a)(4) - The Fel-O-Vax® LvK/FIV vaccine has been subjected to a regulatory review period before its commercial marketing or use.

(f) 35 U.S.C. § 156(a)(5)(A) - The commercial marketing or use of the Fel-O-Vax® LvK/FIV vaccine after the regulatory review period is the first permitted commercial marketing or use under the Virus-Serum-Toxin Act (21 U.S.C. §§ 151-159) under which such regulatory review occurred.

(g) 35 U.S.C. § 156(c)(4) - No other patent has been extended for the same regulatory review period for the Fel-O-Vax® LvK/FIV vaccine.

(12)(ii) The length of the extension of patent term of U.S. Patent No. 5,510,106 claimed by Applicant is that period authorized by 35 U.S.C. § 156(c), which has been

calculated to be 1348 days. The length of the extension was determined pursuant to 37 C.F.R. § 1.779 as follows:

(a) The regulatory review period under 35 U.S.C. § 156(g)(5)(B) began on October 15, 1999, and ended June 23, 2003, which is a total of 1348 days, which is the sum of (1) and (2) below:

(1) The period of review under 35 U.S.C. § 156(g)(5)(B)(i) was zero(0) days; and

(2) The period of review under 35 U.S.C. § 156(g)(5)(B)(ii) began on October 15, 1999, and ended June 23, 2003, which is a total of 1348 days.

(b) The regulatory review period upon which the period of extension is calculated is the entire regulatory review period as determined in subparagraph 12(ii)(a) above (1348 days) less:

(1) The number of days in the regulatory review period which were on or before the date on which the patent issued (April 23, 1996), which is zero (0) days; and

(2) The number of days during which applicant did not act with due diligence, which is zero (0) days; and

(3) One-half the number of days determined in sub-paragraph (12)(ii)(a)(1) above less the number of days in (12)(ii)(b)(1) (one-half of zero (0)), which is zero (0) days;

(c) The number of days as determined in sub-paragraph (12)(ii)(b) (1348) when added to the original term of the patent (January 4, 2011) would result in the date of September 12, 2014.

(d) Fourteen (14) years when added to the date of issuance of a license under the Virus-Serum-Toxin Act (June 23, 2003) would result in the date of June 23, 2017;

(e) The earlier date as determined in sub-paragraphs (12)(ii)(c) and (12)(ii)(d) is September 12, 2014;

(f) Since the patent was issued after November 16, 1988, and since no request for the authority to prepare an experimental biological product under the Virus-Serum-Toxin Act was submitted before November 16, 1988, the period of extension may not exceed five years from the original expiration date of January 4, 2011. Five years when added to the original expiration date of the patent would result in the date of January 4, 2016.

(g) The earlier date as determined by sub-paragraphs (12)(ii)(e) and (12)(ii)(f) is September 12, 2014.

(13) Applicant acknowledges a duty to disclose to the Director of Patents and Trademarks and the Secretary of Agriculture any information which is material to the determination of entitlement to the extension sought.

(14) The fee for receiving and acting upon this application can be charged to Deposit Account No. 20-1430. The Director is authorized to charge any additional fees required by this application to Deposit Account No. 20-1430.

(15) All correspondence and inquiries may be directed to the undersigned, whose address, telephone number and fax number are as follows:

Kevin L. Bastian
Townsend & Townsend & Crew
Two Embarcadero Center, 8th Floor
San Francisco, CA 94111-3834

Telephone: (415) 273 4758
Fax: (415) 576 0300

(16) Enclosed is a certification that the application for extension of patent term under 35 U.S.C. § 156 including its attachments and supporting papers is being submitted as one original and two (2) copies thereof (Attachment H).

Respectfully submitted,

By: _____
Kevin L. Bastian
Reg. No. 34,774

Date: August 20, 2003

Attachments:
Power of Attorney (Attachment A)
Approval Letter and License (Attachment B)
U.S. Patent No. 5,510,106 (Attachment C)
Terminal Disclaimer (Attachment D)
Certificate of Correction (Attachment E)
Receipt of Maintenance Fee Payments (Attachment F)
Chronology of Regulatory Review Period (Attachment G)
Certification of Copies of Application Papers (Attachment H)

PTO/SB/81 (08-03)
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

POWER OF ATTORNEY OR AUTHORIZATION OF AGENT

Application Number	08/335,296 (U.S. Patent 5,510,106)
Filing Date	November 7, 1994 (Issue Date: April 23, 1996)
First Named Inventor	YAMAMOTO
Title	Methods and Compositions For Vaccinating Against Feline Immunodeficiency Virus
Art Unit	1802
Examiner Name	N. Minnifield
Attorney Docket Number	02307U-023770

I hereby appoint:

☒ Practitioners at Customer Number 20350

OR

☐ Practitioner(s) named below:

Name	Registration Number

as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

Please recognize or change the correspondence address for the above-identified application to:

☐ The above-mentioned Customer Number.

OR

☐ Practitioners at Customer Number

☐ Firm *or* Individual Name					
Address					
Address					
City		State		ZIP	
Country					
Telephone		Fax			

I am the:

☐ Applicant/Inventor.

☒ Assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

SIGNATURE of Applicant or Assignee of Record

Name	Linda S. Stevenson		
Signature	Linda S. Stevenson		
Date	August 18, 2003	Telephone	510-587-6000

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of ____ forms are submitted.

PTO/SB/96 (05-03)
Approved for use through 04/30/2003. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Attorney Docket No.

STATEMENT UNDER 37 CFR 3.73(b)

Applicant/Patent Owner: The Regents of the University of California

Application No./Patent No.: 5,510,106 Filed/Issue Date: April 23, 1996

Entitled: Methods and Compositions For Vaccinating Against Feline Immunodeficiency Virus

The Regents of the University of California, a University

(Name of Assignee) (Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest; or
2. ☐ an assignee of less than the entire right, title and interest.
The extent (by, percentage) of its ownership interest is _____%

in the patent application/patent identified above by virtue of either:

A. ☒ An assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the United States Patent and Trademark Office at Reel 7238, Frame 0859, or for which a copy thereof is attached.

OR

B. ☐ A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

1. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

2. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

3. From: _____ To: _____
The document was recorded in the United States Patent and Trademark Office at Reel _____, Frame _____, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are listed on a supplemental sheet.

☐ Copies of assignments or other documents in the chain of title are attached.

[NOTE: A separate copy (*i.e.*, the original assignment document or a true copy of the original document) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the USPTO. See MPEP 302.8]

The undersigned (whose title is supplied below) is authorized to act on behalf of the assignee.

August 20, 2003
Date

510-587-6000
Telephone number

Linda S. Stevenson
Typed or printed name

Linda S. Stevenson
Signature

Manager, Patent Prosecution
Title

USDA

OVERNIGHT MAIL

June 23, 2003

United States Department of Agriculture

Marketing and Regulatory Programs

Animal and Plant Health Inspection Service

Veterinary Services

Center for Veterinary Biologics
Suite 104
510 South 17th Street
Ames, IA 50010
(515) 232-5785
FAX (515) 232-7120

Ms. Madonna Carlson
Fort Dodge Laboratories
800 5th Street, NW
P.O. Box 518
Fort Dodge, IA 50501

Dear Ms. Carlson:

Enclosed is a new United States Veterinary Biological Product License issued this date to Wyeth, Establishment No. 112, authorizing production of the following:

Feline Immunodeficiency-Leukemia Virus Vaccine, Killed Virus, Code 15D5.R0

This U.S. Veterinary Biological Product License does not constitute a patent license. If this product or technology used in the manufacture of this product has been patented or is pending patent, the licensee should obtain a patent license from the patent owner.

If this license does not agree with your records, please return it to this office with your comments.

Sincerely,

Richard E. Hill, Jr., D.V.M.
Director
Center for Veterinary Biologics

Enclosure

United States Department of Agriculture

UNITED STATES VETERINARY BIOLOGICAL PRODUCT LICENSE

Washington, D.C.,

This is to certify that, pursuant to the terms of the Act of Congress approved March 4, 1913 (37 Stat. 832), governing the preparation, sale, barter, exchange, shipment, and importation of viruses, serums, toxins, and analogous products intended for use in the treatment of domestic animals, the person holding United States Veterinary Biologics Establishment License No. 112 *is authorized to prepare in the facilities designated in the establishment license:*

FELINE IMMUNODEFICIENCY-LEUKEMIA VIRUS VACCINE

Killed Virus

Code 15D5.R0

Preparation shall be in accordance with the provisions of the Act, the regulations made thereunder, and additional restrictions or requirements when listed below.

This license is subject to termination as provided in the regulations made under the authority contained in said Act, and to suspension or revocation if the licensee violates or fails to comply with said Act or the regulations made thereunder.

June 23, 2003

Date

Director, Center for Veterinary Biologics
Animal and Plant Health Inspection Service

APHIS FORM 2004
(JUNE 97)

Previous edition may be used.

I hereby certify that this correspondence is being transmitted via facsimile to Examiner Minnifield, Assistant Commissioner for Patents, Washington, D.C. 20231, on October 19, 1995.

By Karen A. Keno
KAREN A. KENO

PATENT

Attorney Docket No. 02307U-023770

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	
JANET K. YAMAMOTO et al.	Examiner: MINNIFIELD, N. M.
Serial No.: 08/335,296	Art Unit: 1813
Filed: November 7, 1994	TERMINAL DISCLAIMER UNDER 37 C.F.R. § 3.73(b)
For: METHODS AND COMPOSITIONS FOR VACCINATING AGAINST FELINE IMMUNODEFICIENCY VIRUS	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Petitioner, Regents of the University of California, is the owner of 100 percent interest in the instant application. Petitioner through their undersigned attorney of record hereby disclaims, except as provided below, the terminal part of the statutory term of any patent granted on the instant application, which would extend beyond the expiration date of the full statutory term defined in 35 U.S.C. 154 to 156 and 173, as presently shortened by any terminal disclaimer, of prior Patent No. 5,275,813. Petitioner hereby agrees that any patent so granted on the instant application shall be enforceable only for and during such period that it and the prior patent are commonly owned. This agreement runs with any patent granted on the instant application and is binding upon the grantee, its successors or assigns.

In making the above disclaimer, petitioner does not disclaim the terminal part of any patent granted on the instant application that would extend to the expiration date of the full statutory term as defined in 35 U.S.C. 154 to 156 and 173 of the prior patent, as presently shortened by any terminal disclaimer,

in the event that it later: expires for failure to pay a maintenance fee, is held unenforceable, is found invalid by a court of competent jurisdiction, is statutorily disclaimed in whole or terminally disclaimed under 37 CFR 1.321, has all claims cancelled by a reexamination certificate, is reissued, or is in any manner terminated prior to the expiration of its full statutory term as presently shortened by any terminal disclaimer.

The Assignment accompanying this Power of Attorney has been reviewed by the undersigned. The undersigned certifies that to the best of the undersigned's knowledge and belief, title is in the Assignee. The undersigned (whose title is supplied below) is empowered to act on behalf of the Assignee.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Date:

Respectfully submitted,

James M. Heslin
Reg. No. 29,541

TOWNSEND and TOWNSEND and CREW
One Market Plaza
Steuart Street Tower, 20th Floor
San Francisco, California 94105
(415) 326-2400

JMH\kk

F:\DATA\PA\PTOD\JMH\18681

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 5,510,106

DATED : April 23, 1996

INVENTOR(S) : Janet K. Yamamoto and Niels D. Pedersen

It is certified that error appears in the above-indentified patent and that said Letters Patent is hereby corrected as shown below:

On the title page, insert item:

--[*] Notice: The term of this patent shall not extend beyond the expiration date of Pat. No. 5,275,813.--

Signed and Sealed this

Seventh Day of October, 1997

Attest:

Attesting Officer

BRUCE LEHMAN

Commissioner of Patents and Trademarks

UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Offi
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

000000

M75M7

TOWNSEND AND TOWNSEND AND CREW LLP
TWO EMBARCADERO CENTER
8TH FLOOR
SAN FRANCISCO CA 94111-3834

MAINTENANCE FEE STATEMENT

The data shown below is from the records of the Patent and Trademark Office. If the maintenance fees and any necessary surcharges have been timely paid for the patents listed below, the notation "PAID" will appear in column 11, "STAT" below.

If a maintenance fee payment is defective, the reason is indicated by code in column 11, "STAT" below. TIMELY CORRECTION IS REQUIRED IN ORDER TO AVOID EXPIRATION OF THE PATENT. NOTE 37 CFR 1.377. THE PAYMENT(S) WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION. IF PAYMENT OR CORRECTION IS SUBMITTED DURING THE GRACE PERIOD, A SURCHARGE IS ALSO REQUIRED. NOTE 37 CFR 1.20(k) and (l).

If the statement of small entity status is defective the reason is indicated below in column 10 for the related patent number. THE STATEMENT OF SMALL ENTITY STATUS WILL BE ENTERED UPON RECEIPT OF ACCEPTABLE CORRECTION.

ITEM NBR	PATENT NUMBER	FEE CDE	FEE AMT	SUR CHARGE	SERIAL NUMBER	PATENT DATE	FILE DATE	PAY YR	SML ENT	STAT
1	5,510,106	183	940	----	08/335,296	04/23/96	11/07/94	04	NO	PAID

ITM NBR	ATTY DKT NUMBER
1	2307U2377

DIRECT THE RESPONSE TOGETHER WITH ANY QUESTIONS ABOUT THIS NOTICE TO: COMMISIONER OF PATENTS AND TRADEMARKS, BOX M. FEE, WASHINGTON, D.C. 20231

BRIEF DESCRIPTION OF ACTIVITIES DURING REGULATORY REVIEW PERIOD FOR FIV/FeLV

Updated 8/15/2003

Date	Description
15-Oct-99	Submitted license application.
15-Oct-99	Submitted new Production Outline.
23-Nov-99	License application received and filed.
22-Dec-99	Outline was approved with comments.
27-Jan-00	Submitted "Efficacy and Non-interference Testing of Fort Dodge Laboratories' Feline Immunodeficiency-Leukemia Virus Vaccine, Killed Virus" protocol.
19-Apr-00	USDA approved the efficacy and non-interference protocol.
3-Jan-01	Submitted request to ship experimental FIV and FeLV/FIV vaccines to Japan.
9-Jan-01	Authorization was given to ship experimental FIV and FeLV/FIV vaccines to Japan.
22-Mar-02	Submitted efficacy report in 8-week-old kittens.
10-May-02	USDA approved the efficacy report in 8-week-old kittens. New in vitro reference approved, expiration date is March 24, 2005.
17-Jun-02	Submitted lack of antigen interference report.
21-Jun-02	Submitted a complete revision to the Outline of Production.
7-Aug-02	USDA has changed the VS Code from 15D5.20 to 15D5.R0 as one of the seeds utilizes biotechnology in its construction and therefore the code should contain an "R".
14-Aug-02	USDA approved Production Outline submitted on June 21.
4-Oct-02	Submitted the field trial request package.
7-Oct-02	USDA approved our lack of antigen interence report submitted on June 17.
11-Oct-02	USDA approved our request to conduct a field safety trial submitted on 10/4/02.
11-Oct-02	In regard to the field trial protocol, USDA recommends that for similar product where you combine 2 licensed products the number of animals required should be 1,000-1,2000.
9-Dec-02	Submitted 3 PLS 2008s (366051, 366052 & 366053) and requested a TA# to submit samples to CVB-L for confirmatory testing.
16-Jan-03	USDA greanted permission to submit samples under TA#8616.
20-Jan-03	Submitted PLS serial samples (366051, 366052 & 366053) to CVB-L for confirmatory testing.
13-Feb-03	USDA confirmed email authorization on 1/16 to submit PLS 366051, 052 & 053 under TA# 8616 for confirmatory testing.
13-Mar-03	Submitted field trial report.
14-Mar-03	Submitted outline changes to include minimum age & new Reference 1475-41-030900.
6/11/2003	Outline changes submitted 3/14 returned approved with no comments.
6/11/2003	Received letter with acceptance to field trial report
6/11/2003	Supplementary field trial report submitted 4/14 returned accepted.
6/23/2003	**Received USDA Licensure of Product.**
6/25/2003	The three prelicensing serials returned approved.